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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,633	04/20/2001	Gregory A. Demopulos	OMER117356	2163

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,633	DEMOPULOS ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22,25-39,41 and 44-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *20,22 and 25-38* is/are allowed.

6)☒ Claim(s) *39,41 and 44-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 20, 22, 25-39, 41 and 44-50 are pending in the instant application. Claims 25, 39, 49 and 50 have been amended as requested by Applicant in the Paper filed January 18, 2005.

Withdrawn Objections and Rejections

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Priority Determination

3. The effective priority date of the instant application for a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising administering sTNFR or rhTNFR:Fc is the filing date of application 60/107,256, November 5, 1998.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4.1 Claims 39 and 41, previously rejected under 35 U.S.C. 102(b), are now rejected under 35 U.S.C. 102(e), filing date May 16, 1996, as being anticipated by Smith et al., U.S. Patent No. 5,945,397, due to change in effective priority date.

Applicants traverse the rejection and submit that Smith et al. clearly envision only systemically administered compositions rather then locally administered compositions, as evidenced by the disclosure at Column 16, lines 12-13, and claim 39 is directed to a solution for use in the preemptive inhibition of pain and inflammation at a wound during a surgical procedure, reflecting local irrigation rather than systemic injection or other systemic administration. Applicants further submit that claim 39 as amended is directed to solutions including the STNFR "at a concentration that is sufficient to provide a level of inhibitory effect at the wound when delivered locally to the wound and that results in a plasma concentration that is less than a plasma concentration that would be required to achieve the same level of inhibitory effect at the wound when delivered systemically.", which would avoid side effects, and thus the instant claims are clearly directed to solutions that are at low concentration and in a liquid irrigation carrier as is suitable for local perioperative irrigation rather than systemic administration and treatment, which are neither disclosed nor suggested by Smith et al.

Applicants' arguments have been fully considered but are not deemed persuasive. Because the specification teaches therapeutic concentrations in a nmolar amounts (page 90, Table 29), but does not teach specific volumes or length of administration, there is no specific concentration administered. Futhermore, Smith et al. does contemplate non-systemic administration, see column 15, line 59 to column 16, line 16, which states:

"For therapeutic use, purified soluble TNF-R protein is administered to a patient, preferably a human, for treatment in a manner appropriate to the indication. Thus, for example,

soluble TNF-R protein compositions can be administered by bolus injection, continuous infusion, **sustained release from implants, or other suitable technique**. Typically, a soluble TNF-R therapeutic agent will be administered in the form of a composition comprising purified protein in conjunction with physiologically acceptable carriers, excipients or diluents. Such carriers will be nontoxic to recipients at the dosages and concentrations employed. Ordinarily, the preparation of such compositions entails combining the TNF-R with buffers, antioxidants such as ascorbic acid, low molecular weight (less than about 10 residues) polypeptides, proteins, amino acids, carbohydrates including glucose, sucrose or dextrins, chelating agents such as EDTA, glutathione and other stabilizers and excipients. Neutral buffered saline or saline mixed with conspecific serum albumin are exemplary appropriate diluents. Preferably, product is formulated as a lyophilizate using appropriate excipient solutions (e.g., sucrose) as diluents. Appropriate dosages can be determined in trials. **The amount and frequency of administration will depend, of course, on such factors as the nature and severity of the indication being treated, the desired response**, the condition of the patient, and so forth.

Therefore Smith et al. does not only disclose systemic administration, but discloses release from implants for example, which would be local administration and which would also release low amounts of the TNF receptor. For these reasons, the instant claims are anticipated by the prior art.

4.2 Claims 39, 41 and 44-50 previously rejected under 35 U.S.C. 102(b), are now rejected under 35 U.S.C. 102(a) as being anticipated by Lai., U.S. Patent No. 5,747,532, due to change in effective priority date.

Applicants traverse the rejection, and assert that the Lai disclosure is clearly directed to compositions delivered for systemic uptake and effect rather than local delivery to the site of a surgical procedure, and for all of the same reasons submitted above with respect to Smith et al., Applicants submit that Claim 39 and dependent claims therefrom define patentable subject matter of Lai.

Applicants' arguments have been fully considered but are not deemed persuasive, for the same reasons as those above in the Smith rejection. Lai et al. contemplates topical administration, which is not systemic and is a local administration, and clearly contemplates

different modes of administration and also clearly contemplates amounts sufficient for types of administration and effect upon the target process, condition or disease.

At column 7, line 59 to column 8, line 28, Lai et al. states:

In accordance with still another embodiment of the present invention, there are provided physiologically active composition(s) comprising an "agent" and a compound having the structure I, as described above, in a suitable vehicle rendering said compound amenable to oral delivery, transdermal delivery, intravenous delivery, intramuscular delivery, **topical delivery**, nasal delivery, and the like.

Depending on the mode of delivery employed, the above-described compositions can be delivered in a variety of pharmaceutically acceptable forms. For example, the above-described compositions can be delivered in the form of a solid, solution, emulsion, dispersion, micelle, liposome, and the like.

Pharmaceutical compositions of the present invention can be used in the form of a solid, a solution, an emulsion, a dispersion, a micelle, a liposome, and the like, wherein the resulting composition contains one or more each of the scavenging and inhibiting compounds contemplated for use in the practice of the present invention, as active ingredients thereof, in admixture with an organic or inorganic carrier or excipient suitable for enteral or parenteral applications. The active ingredients may be compounded, for example, with the usual non-toxic, pharmaceutically acceptable carriers for tablets, pellets, capsules, suppositories, solutions, emulsions, suspensions, and any other form suitable for use. The carriers which can be used include glucose, lactose, gum acacia, gelatin, mannitol, starch paste, magnesium trisilicate, talc, corn starch, keratin, colloidal silica, potato starch, urea, medium chain length triglycerides, dextrans, and other carriers suitable for use in manufacturing preparations, in solid, semisolid, or liquid form. In addition auxiliary, stabilizing, thickening and coloring agents and perfumes may be used. **The active compounds (i.e., "agents" and compounds of structure I as described herein) are included in the pharmaceutical composition in an amount sufficient to produce the desired effect upon the target process, condition or disease.**

For these reasons, the instant claims are anticipated by the prior art.

It is believed that all pertinent arguments have been answered.

Conclusion

5.1 Claims 20, 22, 25-38 are allowed.

5.2 Claims 39, 41 and 44-50 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER